REMARKS

Specification Amendments

The Abstract of the disclosure has been amended to reduce the length thereof as requested by the Examiner.

In addition, a separate heading and section regarding the drawing have been inserted at an appropriate place of the disclosure as requested by the Examiner.

Furthermore, the specification has been amended at multiple places to correct grammatical errors as well as to recite that the final acidic medium after the quenching has a pH value of about 3.0 to about 6.0, preferably about 4 to about 5. Support for such amendment is found in original claim 13 as well as on page 3, lines 6-7; page 6, line 11 and page 14, lines 24-25 of the instant specification. Such amendment is made for the purpose of consistency throughout the specification and claims. No new matter is introduced.

Claim Status

Claims 1 and 13 have been amended to specify that the claimed lysing reagent includes an autoclaved saponin compound. Claims 5 and 14, dependent from claims 1 and 13, respectively, have been amended accordingly to recite that the autoclaved saponin compound is obtained by mixing at a calculated ratio a saponin solution heated at about 121°C for about 30 minutes and an unheated saponin solution. Support for these amendments is found in Example 5, in particular, on page 11, lines 23-26, as well as on page 13, lines 3-6 of the instant specification.

Claims 6-12 have been cancelled.

Claims 2 and 16 have been amended by replacing the term "a" with the phrase --an additional--. Support for such amendment is found on page 3, line 25 and page 4, lines 15-16

of the instant specification, which describes that the third component functioning as a surfactant can be omitted when saponin or a saponin derivative acts as a surfactant. Such description indicates that an additional surfactant (i.e., the optional third component) can be added, which is not saponin or a saponin derivative.

Claims 3 and 17, dependent from claims 2 and 16, respectively, have been amended accordingly to refer to the proper antecedent bases.

Claim 19 has been cancelled.

New claims 20 and 21 have been added. Support for these new claims is found in original claim 13 as well as on page 3, lines 6-7; page 6, line 11; page 14, lines 24-25 and Example 5 of the instant specification.

Applicants respectfully submit that the above amendments do not introduce any new material into the application. With these amendments, there are 13 claims pending, namely claims 1-5, 13-18 and 20-21.

Specification

The Abstract of the disclosure stands objected to because it is too long. In response, Applicants have amended the Abstract according to MPEP § 608.01(b).

The specification stands objected to because it lacks a separate heading and section for the drawing(s). In response, Applicants have amended the specification accordingly.

Claim Objections

Claims 2, 10 and 16 stand objected to as allegedly being of improper dependent form for failing to further limit the subject matter of a previous claim. In response, Applicants have amended claims 2 and 16 to place the claims in proper dependent form by referring to

"an additional surfactant". Claim 10 has been cancelled. As such, the claim objections should be withdrawn.

Claim Rejection – 35 USC §112, First Paragraph (Enablement)

Claims 1, 5, 6-8, 13 and 14 stand rejected under 35 USC §112, first paragraph, as allegedly failing to comply with the enablement requirement. Applicants respectfully traverse this rejection.

Claims 1 and 13 have been amended to specify that the claimed lysing reagent includes an autoclaved saponin compound. Claims 5 and 14, dependent from claims 1 and 13, respectively, have been amended accordingly to recite that the autoclaved saponin compound is obtained by mixing at a calculated ratio a saponin solution heated at about 121°C for about 30 minutes and an unheated saponin solution. Claims 6-12 have been cancelled.

As presently amended, the instant claims no longer refer to any saponin compound that is heated to any temperature; rather, the amended claims refer to an autoclaved saponin compound. It is expected that the autoclave procedure, being an intensive heating procedure, reduces the saponin activity, possibly by removing the unstable lytic components from saponin. As such, the remaining lytic components in saponin may have a longer stability in solution. In fact, page 13, lines 3-6 of the instant specification describes that "no apparent loss of lytic strength was revealed for the autoclaved saponin derivatives for 47 days at 40°C. In contrast a measurable amount of loss of lytic strength was observed for the un-autoclaved saponin."

In addition, Applicants submit that at the time of the filing of the present application, autoclaving technique was well known in the art. Along with the guidance provided in the

instant specification (especially in Example 5), one of ordinary skill in the art would, without undue experimentation, know how to produce a stabilized saponin compound with the desired hemolytic activity by autoclaving. It is further noted that dependent claims 5 and 14, as presently amended, spell out some of the conditions for the autoclave procedure.

In view of the above amendments and remarks, the instant claims are commensurate in scope with the enabling disclosure. As such, the rejection under 35 USC §112, first paragraph, should be withdrawn.

Claim Rejection – 35 USC §102

Claims 1-3, 6, 7, 9-11, 13, 15-17 and 19 stand rejected under 35 USC §102(e) as allegedly being anticipated by Crews et al. (US 2002/009589, "Crews"). Applicants respectfully traverse this rejection.

As discussed above, claims 1 and 13 have been amended to specify that the claimed lysing reagent includes an autoclaved saponin compound. Claims 5 and 14, dependent from claims 1 and 13, respectively, have been amended accordingly to recite that the autoclaved saponin compound is obtained by mixing at a calculated ratio a saponin solution heated at about 121°C for about 30 minutes and an unheated saponin solution. Claims 6-12 and 19 have been cancelled. New claims 20 and 21 have been added, which are directed to methods of preparing a whole blood sample for leukocyte analysis by substantially lysing red blood calls using an autoclaved saponin compound and an acid, followed by substantially quenching the lysing by bringing the final pH value to about 3 to about 6. Applicants extend the following remarks to the newly added claims 20 and 21.

Crews discloses a lytic reagent system for selective chemical treatment of a whole blood sample, which comprises a lytic reagent and a quenching reagent. Crews also

discloses a method for determining leukocytes and hemoglobin in blood using a lysing agent. Although it discloses that the lytic reagent or lysing agent comprises saponin, Crews does not teach or suggest that the saponin component is autoclaved to achieve improved stability.

In contrast, the present application claims a hematology reagent and method with improved properties, which reagent and method involve an autoclaved saponin compound. As discussed above, the autoclave procedure provides an improved stability of the saponin compound as compared to un-autoclaved saponin. Also *see*, page 13, lines 3-6 of the instant specification.

In addition, Crews teaches that the addition of a quenching reagent is required in order to adjust the pH to approximately neutral (i.e., 6.5 to 7.5) for final measurement. *See*, paragraphs [0009] and [0075] of Crews. In contrast, the instant invention teaches that a final acidic medium is critical for stabilizing white blood cells and continuously removing red blood cell fragments from the blood sample. *See*, page 1, lines 23-25; page 2, lines 14-16; page 5, lines 20-22; page 6, lines 11-13; and page 13, lines 13-15 of the instant specification. It would be reasonable for one skilled artisan to expect that Crews' system and method differ from the instant system and method, as Crews teaches a near neutral final environment after the quenching, whereas the instant invention teaches and further claims a final acidic medium after the quenching. Furthermore, the instant invention teaches as well as claims that the preferred pH for the final solution is about 4 to about 5. In view of all these, Applicants believe that the claimed pH range of about 3 to about 6 (*see*, instant claim 13 and newly added claims 20-21) would reasonably be excluding a pH value of "about 6.5" as disclosed by Crews, as such value is taught to be a near neutral pH by Crews. With the repeated descriptions of the final medium being acidic in the instant specification, the metes and

bounds of the term "about" as recited in the instant claims are believed to be implicitly defined.

In view of the above amendments and remarks, the instant claims are not anticipated by Crews. As such, the rejection under 35 USC §102(e) should be withdrawn.

Claim Rejection – 35 USC §103

Claims 1-4, 6, 7, 9-13 and 15-19 stand rejected under 35 USC §103(a) as allegedly being unpatentable over Crews et al. (US 2002/009589, "Crews"), as applied to claims 1-3, 6, 7, 9-11, 13, 15-17 and 19, further in view of Malin et al. (U.S. Pat. No. 5,639,630, "Malin"). Applicants respectfully traverse this rejection.

As discussed above, Crews does not teach or suggest the use of autoclaved saponin for its hemolytic reagent system and method.

Malin teaches method and reagent composition for performing leukocyte differential counts on whole blood samples. Although it teaches the use of a nonionic polyethoxylate surfactant for lysing red blood cells while preserving white blood cell populations, Malin does not teach or suggest the use of any saponin compound for lysing, let alone the use of an autoclaved saponin compound. That is, Malin does not compensate the deficiency of Crews. As such, Crews, further in view of Malin, do not render obvious the present application as claimed. Accordingly, the rejection under 35 USC §103(a) should be withdrawn.

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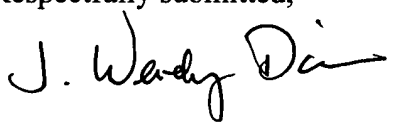
This document is filed timely and no fee is believed to be due. However, should any fees be required for any reason, the Commissioner is authorized to deduct said fees from Howrey Deposit Account No. 08-3038/12642.0066.NPUS01.

Respectfully submitted,



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